

REMARKS

Applicant amended the title and amended independent claim 7 to further define Applicant's claimed invention. Support for an orthopedic implant for engaging at least one non-vertebral bone of the human body is found in the specification at least on: page 20, lines 8-9 (general skeletal use other than in the anterior cervical spine); page 32, lines 12-15 (long bone such as a humerus); page 34, lines 7-10 (any contour...appropriate for skeletal use); page 36, lines 3-6 (conform to bone(s) B to which they are applied); Fig. 33 (long bone shown); Fig. 55 (long bone shown); and Figs. 70E and 70F (long bone shown). Applicant respectfully submits that the Examiner's contention that "applicant only has support for bone outside of the anterior cervical spine not the entire spine nor outside a human specifically" is misplaced. (Advisory Action, Continuation Note 3). It is submitted that the amendment to claim 7 is fully supported by the specification and is not new matter.

In the Final Action dated March 20, 2006 ("Final Action"), the Examiner rejected claims 7-41 under the judicially created doctrine of obviousness-type double patenting over:

- claims 1-221 of U.S. Patent No. 6,592,586;
- claims 1-20 of U.S. Patent No. 6,926,718;
- claims 1-39 of U.S. Patent No. 6,936,050;
- claims 1-39 of U.S. Patent No. 6,936,051;
- claims 1-220 of U.S. Patent No. 6,527,776;
- claims 1-124 of U.S. Patent No. 6,454,771;
- claims 1-117 of U.S. Patent No. 6,398,783;
- claims 1-25 of U.S. Patent No. 6,139,550; and
- claims 1-173 of U.S. Patent No. 6,193,721.

The Examiner provisionally rejected claims 7-41 under the judicially created doctrine of obviousness-type double patenting over:

- claims 1-20 of co-pending Application No. 11/110,161;

claims 31-44, 174, 175, and 232-245 of co-pending Application No. 10/160,059;

claims 1, 3-8, 11-18, 20-24, 26-60, 65-81, 199-215, 217-237, 242-252, 254-256, and 261-363 of co-pending Application No. 10/160,247; and

claims 1-8, 11-75, 183-188, 190-193 195-197, 201-241, and 244-277 of co-pending Application No. 10/160,407.

In the Advisory Action dated August 20, 2006 ("Advisory Action"), the Examiner indicated that Applicant's Reply of August 7, 2006, overcame the double patenting rejection under U.S. Patent No. 6,592,586. The double patenting rejection under U.S. Patent No. 6,139,550 has been overcome by Applicant's submission of a Terminal Disclaimer disclaiming the term of any patent granted on the present application that would extend beyond the term of '550 patent, thereby rendering the Examiner's rejection in view of the '550 patent moot.

A. Double Patenting Rejections

Applicant respectfully traverses the Examiner's double patenting rejections as to the remaining patents and applications listed above (the "listed patents and applications") for at least the reasons set forth below.

1. The claims of the present application and the claims of the listed patents and applications are directed to inventions in different fields of surgery.

Independent claim 7, as now amended, recites "an orthopedic implant for engaging at least one non-vertebral bone of the human body" and having a bone-contacting surface "adapted to be placed against the at least one non-vertebral bone." All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of U.S. Patent No. 6,527,776, are directed to inventions for application in the "anterior human cervical spine." The distinctness of the claims of the '776 patent are discussed below. Applicant submits that the field of spinal surgery and other fields of skeletal surgery not involving the spine are distinct and non-analogous. Accordingly, Applicant submits that the claims of the present application would not have been obvious in view of the claims of the listed patents and applications.

2. The claims of the present application are mutually exclusive relative to those of the listed patents and applications.

Independent claim 7 of the present application recites “a substantial portion of said bone-contacting surface being one of flat and convex along the length of said body.” According to the MPEP, “[t]he general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first.” (MPEP § 806.04(f) “Claims Restricted to Species, by Mutually Exclusive Characteristics” (August 2001)). The bone-contacting surface being one of flat and convex as recited in claim 7 of the present application is a feature that is exclusive to areas outside of the anterior cervical spine due to the concave curvature of the anterior cervical spine. All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of the ‘776 patent, are directed to inventions for application in the “anterior human cervical spine.” The distinctness of the claims of the ‘776 patent are discussed below. Accordingly, Applicant submits that the claims of the present application and those of the listed patents and applications are directed to inventions having mutually exclusive characteristics and are therefore patentably distinct.

3. The claims of the present application are not “generic” to the claims of the listed patents and applications.

The Examiner contends that “the inventions of the patents are in effect a ‘species’ of the ‘generic’ invention of claims 7-41 in the application.” (Office Action, page 3, paragraph 1). As set forth above, independent claim 7 is directed to “an orthopedic implant for engaging at least one non-vertebral bone of the human body” and having a bone-contacting surface “adapted to be placed against the at least one non-vertebral bone.” All the independent claims from the remaining listed patents and applications, with the exception of the independent claims of the ‘776 patent, are directed to inventions for application in the “anterior human cervical spine.” The distinctness of the claims of the ‘776 patent are discussed below. Applicant submits

that the claims of the present application are not "generic" to the claims of the listed patents and applications, and therefore are not "anticipated" by the "species" of the listed patents and applications.

4. The claims of the '776 patent are patentably distinct from the claims of the present application.

The claims of the present application are drawn to an implant including a locking element for locking at least two bone screws. The claims of the '776 patent are directed to a locking element adapted to retain at least two bone screws. The '776 patent is a divisional of U.S. Patent No. 6,193,721. During prosecution of the '721 patent, the Office mailed a Restriction Requirement restricting the claims. A copy of the Restriction Requirement is attached hereto as **Exhibit A**. The Restriction Requirement designated at least the following subject matter as patentably distinct: (1) a plate system including a plate with a locking element adapted to lock at least two bone screws (species (a)); (2) a locking element (Group VI); and (3) a plate system including a plate with a locking element adapted to lock only a single bone screw (species (b)). Applicant submits that the Restriction Requirement mailed by the Office during the prosecution of the '721 patent shows that the subject matter of the present application is patentably distinct from the subject matter of the '776 patent.

Moreover, Applicant submits that the claims of the '776 patent are patentably distinct from the claims of the present application because the claims of both the present application and the '776 patent meet the combination/subcombination test for distinctness. According to the MPEP:

"[t]he inventions are distinct if it can be shown that a combination as claimed:

(A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and

(B) the subcombination can be shown to have utility either by itself or in other and different relations."

(MPEP § 806.05(c) (August 2001)).

The present application includes a claim to the combination having an implant including a locking element for locking at least two bone screws. Independent claim 1

of the '776 patent is directed to a locking element having "a first dimension and a second dimension" where "said second dimension" is "greater than said first dimension." Independent claim 56 of the '776 patent is directed to a locking element having "at least one flexible portion formed by at least one slot passing through at least a portion of said thickness of said locking element." Independent claim 111 of the '776 patent is directed to a locking element having a lower facing surface "being at least in part ramped and adapted to slide over at least a portion of a bone screw inserted into one of the bone screw receiving holes." Independent claim 166 of the '776 patent is directed to a locking element having a lower facing surface "being at least in part cammed and adapted to slide over at least a portion of a bone screw inserted into one of the bone screw receiving holes."

None of the features of independent claims 1, 56, 111, and 166 of the '776 patent are required for patentability of independent claim 7 of the present application. Accordingly, the part A of the test set forth above is satisfied. Moreover, Applicant submits that the locking element claimed in the '776 patent has utility by itself. For example, the locking element claimed in the '776 patent can be part of an anterior cervical plate. Thus, part B of the test set forth above is satisfied. Accordingly, Applicant submits that both parts of the test for distinctness are satisfied and that the subject matter of the claims of the present application are patently distinct from the claims of the '776 patent.

Applicant submits that independent claim 7 is patentable and that dependent claims 8-41 dependent from independent claim 7, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any

fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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By: 
Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030